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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/787,866 | 03/22/2001 | Maria Emanuel Ryan | 178-261 PCT/ | 8018 |

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1614 | 9 |

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/787,866 | RYAN ET AL. |
| | Examiner Cybille Delacroix-Muirheid | Art Unit 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 May 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-36 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) Other: _____

Detailed Action

1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.
2. Claims 15,16,17, 32-34 are objected to because of the following informalities: said claims refer to structures which are not in the claims themselves but are provided separately at the end of the application. It is respectfully requested that Applicant incorporate the structures into drawings (figures) and the claims should be amended to refer to the figures in which the structures may be found. Appropriate correction is required.
3. Claims 15, 16, 32, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received May 5, 2003.
No claims are cancelled. No new claims are added. Claims 1-36 are currently pending.

The Examiner has expanded the search to the non-elected species. Accordingly, claims 5-9, 15-17, 22-26 and 32-36 are presented for prosecution on the merits.

Concerning priority, Applicant is respectfully reminded to amend the specification by specifically referring to the provisional application filed under 35 USC 119(e). Please refer to paragraph 1 of the office action mailed Jan. 29, 2003.

The previous objection set forth in paragraph 3 of the office action mailed Jan. 29, 2003 is maintained for reasons already of record.

The previous claim rejection under 35 USC 112, paragraph 2, set forth in paragraphs 4-5 of the office action mailed Jan. 29, 2003 is maintained for reasons already of record.

The previous rejection of claims 1-4, 11-14 under 35 USC 103(a) set forth in paragraph 8 of the office action mailed Jan. 29, 2003 is **withdrawn** in view of Applicant's amendment and the remarks contained therein. Upon review of the provisional application 60/102056 it is clear that method claims 1-17 and 35 have support in the provisional application and are thus entitled to the filing date of Sept. 28, 1998. The Ryan et al. patent is therefore properly excluded under 35 USC 103(c).

However, claims 18-34 and 36 drawn to methods of "treating cataract formation" do not have support in the provisional application. The method described in the provisional is a prophylactic method of reducing the risk of cataract development, which does not implicitly include a method of treating mammals that are already suffering from cataracts. Therefore, these claims are only entitled to an effective filing date of Sept. 28, 1999. Since the exclusion under 35 USC 103(c) does not apply to references qualifying as prior art under 35 USC 102(a), the Ryan et al. reference remains available as prior art.

In view of the above, the following new ground of rejection is submitted.

New Ground of Rejection

Upon further consideration of the Ryan et al. reference, the previous objection to claims 10 and 27 set forth in paragraph 9 of the office action mailed Jan. 29, 2003 is withdrawn and the following new ground of rejection follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

I. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al, 5,929,055.

Ryan et al. disclose a therapeutic method for the management of diabetes. Specifically, Ryan et al. disclose a method of reducing the development or progression of a diabetes-associated pathological complication in a mammal. The method comprises administering effective amounts, i.e. an amount that has substantially no antimicrobial activity, of a tetracycline compound such as tetracycline, doxycycline, minocycline or derivatives such as 4-dedimethylamino-tetracycline, etc. Examples of pathological complications are various nephropathies, various retinopathies and **cataract of the lens of the eye**. Ryan et al. disclose that the tetracycline derivatives serve to ameliorate or reduce/eliminate the pathological complications. Finally, the tetracycline derivatives may be administered orally, topically, by injection or the derivatives may be administered by time-release or controlled delivery formulations. The amount of tetracycline compound administered should be effective to treat the

pathological condition while avoiding antimicrobial activity. Please see col. 5, lines 39-47; col. 6, lines 28-33; col. 7, lines 40-44; col. 9, lines 20-54; col. 13, lines 15-67; col. 14, lines 39-44.

Ryan et al. do not specifically disclose that the method reduces the risk of cataract development nor does Ryan et al. specifically disclose a cataract treatment method; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select any of the pathological conditions, specifically cataracts, taught by Ryan et al. because one of ordinary skill in the art would have the reasonable expectation that any of the pathological conditions, especially cataracts, would be treated by the disclosed method. Moreover, Ryan et al. raise reasonable expectation of success by suggesting that the disclosed tetracycline compounds or derivatives thereof would treat cataracts.

With respect to reducing the risk of cataract development, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the tetracycline derivatives prophylactically because one of ordinary skill in the art, based on the desirable teachings of Ryan et al. would reasonably expect the tetracycline derivatives to not only treat cataracts in diabetic patients but also reduce the risk of their development. This is further evidenced by Ryan et al. at col. 7, line 42-43, where it is disclosed that the pathological condition would be "reduced."

Claim Rejection—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 14, 16, 18, 24, 25, 31, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by HCAPLUS Online abstract DN 76:30596 (1972) for Smirnov, Makro-Mikrostrukt. Tkanei Norme, Patol. Eskip. (1969), 34-43 (aka Smirnov abstract).

The Smirnov abstract discloses a method of treating rabbits with burn induced corneal cataracts by administering a composition containing collagenase or lidase and tetracycline. Results indicate that visual activity and acuity increased in the treated rabbits. Please see the abstract submitted herewith.

Claims 18, 24, 25, 31, 33 are anticipated because Smirnov discloses administration of an identical agent to a mammal in need thereof using the claimed method steps. Therefore, a reduction in further cataract development would be inherent.

Please also note that the claims recite “comprising” language. The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450

(Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Conclusion

Claims 1-36 are rejected.

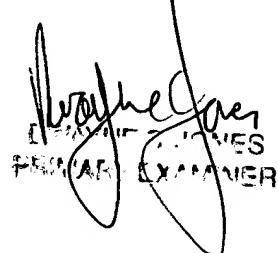
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Sep. 6, 2003



Handwritten signature of Cybille Delacroix-Muirheid. The signature is written in cursive ink and appears to read "Cybille Delacroix-Muirheid". Below the signature, the text "PRIMARY EXAMINER" is printed in a smaller, uppercase font.